

Docket No. AZ-0017

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Frank Jao et al.

Serial No. : 10/628,970

Art Unit: Not Yet Assigned

Filed : July 28, 2003

Examiner: Not Yet Assigned

For : FORMULATIONS AND DOSAGE FORMS FOR CONTROLLED  
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February 20, 2004

(Date of Deposit)

Mary A. Appollina

(Name of applicant, assignee, or Registered Representative)

*Mary A. Appollina*  
(Signature)

February 20, 2004

(Date of Signature)

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37  
C.F.R. §§1.97-1.98, information relating to the above-identified  
application is hereby disclosed. Inclusion of information in  
this statement is not to be construed as an admission that this  
information is material as that term is defined in 37 C.F.R.  
§1.56(b).

Applicant(s) reserve(s) the right to establish the  
patentability of the claimed invention over any of the  
information provided herewith, and/or to prove that this  
information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not

enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language.

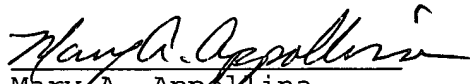
☐ The relevance of those listed references which are not in the English language is as follows:

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

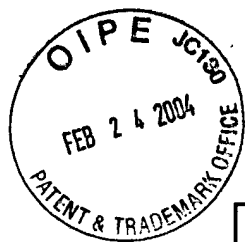
☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/AZ-0017/MAA. This form is submitted in triplicate.

Respectfully submitted,

  
Mary A. Appollina  
Reg. No. 34,087  
Attorney for Applicants

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-3742  
DATED: February 20, 2004



PTO-SB-08A (08-00)

Approved for use through 10-31-2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A-PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 4

Application Number	10/628,970
Filing Date	July 28, 2003
First Named Inventor	Frank JAO
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	AZ0017USANP

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	6,559,293	B1	ALMARSSON et al.	05-06-2003	
	AB	2003/0072802	A1	CUTLER	04-17-2003	
	AC	6,210,712	B1	EDGREN et al.	04-03-2001	
	AD	6,174,547	B1	DONG et al.	01-16-2001	
	AE	5,938,654		WONG et al.	08-17-1999	
	AF	5,614,578		FERRARI et al.	03-25-1997	
	AG	5,413,672		HIROTSUJI et al.	05-09-1995	
	AH	5,391,381		WONG et al.	02-21-1995	
	AI	5,387,700		MARYANOFF et al.	02-07-1995	
	AJ	5,340,590		WONG et al.	08-23-1994	
	AK	5,324,280		WONG et al.	06-28-1994	
	AL	5,252,338		JAO et al.	10-12-1993	
	AM	5,190,765		JAO et al.	03-02-1993	
	AN	5,160,743		EDGREN et al.	11-03-1992	
	AO	5,156,850		WONG et al.	10-20-1992	
	AP	5,110,597		WONG et al.	05-05-1992	
	AQ	5,082,655		AGARWALA et al.	01-21-1992	
	AR	5,024,842		EDGREN et al.	06-18-1991	
	AS	5,023,088		WONG et al.	06-11-1991	
	AT	5,019,397		WONG et al.	05-28-1991	
	AU	5,006,346		EDGREN et al.	04-09-1991	

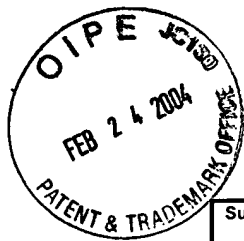
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 4

Application Number	10/628,970
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First Named Inventor	Frank JAO
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Examiner Name	Not yet assigned
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		Number	Kind Code <sup>2</sup> (if known)			
	AV	4,961,932		THEEUWES	10-09-1990	
	AW	4,957,494		WONG et al.	09-18-1990	
	AX	4,940,465		THEEUWES et al.	07-10-1990	
	AY	4,931,285		EDGREN et al.	06-05-1990	
	AZ	4,915,949		WONG et al.	04-10-1990	
	BA	4,892,778		THEEUWES et al.	01-09-1990	
	BB	4,853,229		THEEUWES et al.	08-01-1989	
	BC	4,824,675		WONG et al.	04-25-1989	
	BD	4,681,583		URQUHART et al.	07-21-1987	
	BE	4,578,075		URQUHART et al.	03-07-1978	
	BF	4,519,801		EDGREN	05-28-1985	
	BG	4,513,006		MARYANOFF et al.	04-23-1985	
	BH	4,327,725		CORTESE et al.	05-04-1982	
	BI	4,207,893		MICHAELS	06-17-1980	
	BJ	4,160,020		AYER et al.	07-03-1979	
	BK	4,111,202		THEEUWES	09-05-1978	
	BL	4,111,201		THEEUWES	09-05-1978	
	BM	4,088,864		THEEUWES	05-09-1978	
	BN	4,077,407		THEEUWES et al.	03-07-1978	
	BO	4,008,719		THEEUWES et al.	02-22-1977	
	BP	4,002,173		MANNING et al.	01-11-1977	
	BQ	3,995,631		HIGUCHI	12-07-1976	

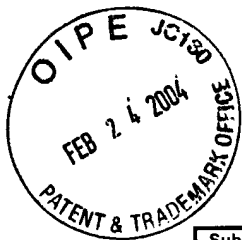
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Sheet 3 of 4

Application Number	10/628,970
Filing Date	July 28, 2003
First Named Inventor	Frank JAO
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	AZ0017USANP

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		Number	Kind Code <sup>2</sup> (if known)			
	BR	3,916,899		THEEUWES et al.	11-04-1975	
	BS	3,865,108		HARTOP	02-11-1975	
	BT	3,845,770		THEEUWES et al.	11-05-1974	
	BU	3,546,142		MICHAELS et al.	12-08-1970	
	BV	3,541,006		BIXLER et al.	11-17-1970	
	BW	3,541,005		STRATHMANN et al.	11-17-1970	
	BX	3,276,586		ROSEAN	10-04-1966	
	BY	3,173,876		JACKSON	03-16-1965	
	BZ	3,133,132		LOEB et al.	05-12-1964	
	CA	2,799,241		WURSTER	07-16-1957	

**FOREIGN PATENT DOCUMENTS**

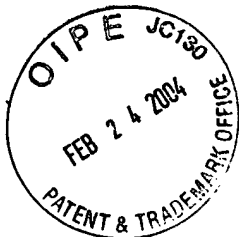
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
	CB	WO	00/72841		Jeffrey Berlant	12-07-2000		
	CC	WO	00/48607	A	Tovama Farmaceutskih et al.	08-24-2000		
	CD	WO	00/25790	A	ALZA Corporation	05-11-2000		
	CE	WO	99/62496	A1	ALZA Corporation	12-09-1999		
	CF	WO	99/44581	A2	Ortho-McNeil Pharmaceutical, Inc.	09-10-1999		
	CH	WO	98/14168	A2	ALZA Corporation	04-09-1998		
	CI	WO	98/06380	A2	ALZA Corporation	02-19-1998		

Examiner  
SignatureDate  
Considered

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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 4 of 4

Application Number	10-628,970
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First Named Inventor	Frank JAO
Group Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket Number	AZ0017USANP

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published	T <sup>2</sup>
	CJ	Encyclopedia of Polymer Science and Technology, "Cellulose Esters, Organic," 3:325-354, Interscience Publishers, NY, 1964	
	CK	Klaus Florey Ed., <u>Analytical Profiles of Drug Substances</u> , 13:425, Academic Press, New York, 1984.	
	CN	BASF Technical Bulletin "PLURONIC® and PLURONIC® R Block Copolymer Surfactants" BASF Corporation, 1998-2003.	
	CO	BASF Technical Bulletin "TETRONIC® and TETRONIC® R Block Copolymer Surfactants" BASF Corporation, 1998-2003.	
	CQ	Scott & Roff, <u>Handbook of Common Polymers</u> , CRC Press., Cleveland Ohio, 1971.	
	CR	Larry Hixon, et al., "Sizing Materials by Crushing and Grinding", <u>Chemical Engineering</u> , 94-103, November 1990.	
	CS	Eugene L. Parrott, "Milling of Pharmaceutical Solids", <u>Journal of Pharmaceutical Sciences</u> , 61(6):813-829, 1974.	
	CT	<u>Perry's Chemical Engineers Handbook</u> , Perry, Green & Maloney Editors, et al, 6 <sup>th</sup> Ed., "Introduction to Screening and Wet Classification", pp. 21.13 to 21.19, 1984..	
	CU	Remington's Pharamaceutical Sciences, 18 <sup>th</sup> Ed, Ch 91, "Sustained-Release Drug Delivery Systems: Oral Dosage Forms" pp.1682-1685, 1990.	
	CV	Remington's Pharamaceutical Sciences, 17 <sup>th</sup> Ed, Ch. 89, "Powders," pp. 1585-1594, 1985.	
	CW	<u>Physician's Desk Reference</u> , Medical Economics-Thompson Healthcare, 56 <sup>th</sup> Ed., "TOPOMAX®," pp. 2590-2595 and "Dilantin-125"p. 2626, 2002.	
	CX	Giancarlo Santus & Richard W. Baker, "Osmotic drug delivery: a review of the patent literature," <u>Journal of Controlled Release</u> , 35:1-21, 1995.	
	CY	Dale E. Wurster, "Air-Suspension Technique of Coating Drug Particles", <u>J. Am. Pharm. Assoc.</u> , 48(8):451-454, August 1959.	
	CY	Dale E. Wurster, "Preparation of Compressed Tablet Granulations by the Air-Suspension Technique II", <u>J. Am. Pharm. Assoc.</u> , 49(2):82-84, February 1960.	

Examiner Signature		Date Considered	
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<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



<b>SUBMISSION UNDER MPEP 609 D</b>  Page 1 of 1	<i>Application Number</i>	10/628,970
	<i>Filing Date</i>	July 28, 2003
	<i>First Named Inventor</i>	Frank Jao et al.
	<i>Group Art Unit</i>	
	<i>Examiner Name</i>	
	<i>Attorney Docket Number</i>	AZ-17

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	U.S. Patent Document		Pages, Columns, Lines, where relevant passages or relevant figures appear
			Number	Kind Code <sup>2</sup> (if known)	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Name of Patentee or Applicant of Cited Document	Foreign Patent Document			Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
			Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>		

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner 's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
		PCT International Search Report, dated November 28, 2003, for PCT Int'l. Appln. No. PCT/US03/23438	

Examiner Signature		Date Considered	
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